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EXAMINER

LOGIE, MICHAEL J

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,974	<b>Applicant(s)</b> AMELIA ET AL.	
	<b>Examiner</b> MICHAEL J. LOGIE	<b>Art Unit</b> 2881	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-14,17 and 20-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-14,17 and 20-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

An "Amendment" was received on 03 January 2011, in response to Office Action of 01 October 2010. Claims 1, 3, 21, 22, 31 and 32 have been amended. Claim 41 has been newly added. Claims 1, 3-5, 7-14, 17, 20 and 21-41 are now pending.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 3-5, 7-14, 17, 20 and 21-41 have been considered but are moot in view of the new ground(s) of rejection.

The examiner agrees '263 does not teach two different materials for two separate parts of the insert. However '263 does teach two parts as claimed (i.e. the chamber region 1 of insert 8 and the discharge channel portion of insert 8 formed between the diffuser and the second part of the insert (That is, two different functional pieces of the insert provide two parts to the insert)). Further Zeisler does teach a two part insert. Page 451; figure 2 shows a copper holding ring and a niobium target chamber. Since '263 already teaches the integral two part ring made of silver or titanium (see page 4, line 28-29), '263 only needs to be modified to provide a second part different metal material target chamber. Zeisler provides a two part ring and chamber insert made of two different materials, where one is niobium as required by some of the claims.

Upon further search an alternate patent Erdman (USPN 6,586,747) was found which is used as an alternate secondary reference also teaching a two part insert of different materials. A detailed discussion is laid out herein below with regards to both Zeisler and Erdman.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 9-11, 13, 14, 17, 20-22, 27-32 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over BE 1011263 A6 (translation submitted by applicant on 12/16/2009)(herein '263) and further in view of Zeisler et al. (Zeisler et al., "A water-cooled spherical niobium target for the production of [18F]fluoride", Applied Radiation and Isotopes 53 (2000) 449-453)(copy of publication submitted with the office action of 10/01/2010) or in alternate Erdman (USPN 6,586,747).

In regards to claim 1, '263 teaches an irradiation cell (fig. 1) for producing a radioisotope of interest through the irradiation of a target material by a particle beam (page 2, lines 8-12), the irradiation cell comprising a target body (page 5, line 14), a diffuser configured to provide a path for a cooling medium (page 4, lines 25-27), and a removable metallic insert (fig. 1,8, figure 2 shows an exploded view thus removable, further an insert is removable by definition) comprising a cavity designed to house the target material (page 4, lines 10-11 and page 4, lines 28-30 teach the cavity holds the target and the cavity is made with an insert) and the cavity closed by an irradiation window (page 4, lines 10-11 teach a charged particle beam sent to a target within a cavity, thus the cavity must inherently be closed by an irradiation window to allow the

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charged particle beam access to the cavity), the metallic insert configured to be inserted in and removed from the target body (where an insert can be inserted, it can be removed from the body, thus the limitation is interpreted to be met), wherein the removable metallic insert comprises of at least a first part (the insert part forming the target cavity is the first part) and a second part (portion of the insert forming the cooling channel see page 5, lines 7-14), the first part having an elongated cavity that is longer in a direction parallel to the particle beam that irradiates the target than in a direction perpendicular to the particle beam (as seen in figure 1) and the second part surrounding the first part and forming a channel configured to guide a cooling medium (page 5, lines 7-14).

'263 differs from the claimed invention by not disclosing the metallic insert having at least two separate metallic parts of different materials.

However, Zeisler teaches the metallic insert having at least two separate metallic parts of different materials (fig. 2, page 451, wherein the first part is the target chamber 5 and the second part is the holder ring 3).

Also Erdman teaches the metallic insert (fig. 3, 56 is inserted between elements 68 and 40) at least two separate metallic parts of different materials (fig. 3, 56 and 64, wherein 64 is made of niobium (col. 5, lines 63-65) and 56 is made of any other chemically inert material, like silver (col. 6, lines 17-28)).

Zeisler or Erdman modify '263 by providing a two part insert of different materials.

Since both '263 and Zeisler teach target chambers, it would have been obvious to one of ordinary skill in the art to have the two part arrangement of Zeisler in '263 at

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the time the invention was made because it would provide cooling water to all sides of the target chamber (see section 2 on page 450). Further the claim would have been obvious because the substitution of one known element (i.e. integral insert) with another (two part ring and chamber insert) would have yielded predictable results to one of ordinary skill in the art at the time of the invention (i.e. cooling to all sides of the chamber).

Since both '263 and Erdman teach target chambers, it would have been obvious to one of ordinary skill in the art to have the two part arrangement of Erdman in '263 at the time the invention was made because it would provide for a cooling fluid channel that draws heat away from the rear window 64 and thus from the liquid target (col. 7, lines 44-52). Further the claim would have been obvious because the substitution of one known element (i.e. integral insert) with another (two part holder body and window insert) would have yielded predictable results to one of ordinary skill in the art at the time of the invention (i.e. cooling the rear window).

In regards to claims 3, 22 and 32, '263 teaches wherein said cell further comprises a coolant supply configured to supply the cooling medium (fig. 1, 10) and the coolant supply in connection with the channel the diffuser device surrounding the first part and being configured to guide the cooling medium around the first part (page 5, lines 1-6), and wherein the second part surrounds both the first part and the diffuser device in a manner to form a return path for the cooling medium between the diffuser device and the second part (page 5, lines 7-14).

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In regards to claims 9, 27 and 37, '263 teaches wherein the first part comprises a flat, circular and ring-shaped portion having an inner circular edge and an outer circular edge, a cylindrical portion rising perpendicularly from the inner circular edge of the flat portion, and a hemispherical portion being on top of the cylindrical portion, the cavity being formed inside the cylindrical and hemispherical portions (as seen in figure 1).

In regards to claims 10 and 28, '263 differs from the claimed invention by not disclosing wherein the cylindrical portion has a wall thickness comprised between .3 and .7 mm.

However, Zeisler et al. teach wherein the cylindrical portion has a wall thickness comprised between .3 and .7 mm (page 450, section 4 shows an equation wherein the wall thickness is a variable, as such .3 to .7 mm is a possible range of wall thicknesses).

Zeisler modify '263 by providing a two part insert of different materials.

Since both '263 and Zeisler teach target chambers, it would have been obvious to one of ordinary skill in the art to have the two part arrangement of Zeisler in '263 at the time the invention was made because it would provide cooling water to all sides of the target chamber (see section 2 on page 450). Further the claim would have been obvious because the substitution of one known element (i.e. integral insert) with another (two part ring and chamber insert) would have yielded predictable results to one of ordinary skill in the art at the time of the invention (i.e. cooling to all sides of the chamber).

In regards to claims 11 and 29, '263 teaches wherein the second part has the form of a hollow cylinder having two flat sides essentially perpendicular to a cylindrical

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side, the cylinder being connected by one flat side against the flat portion of the first part (as seen in figure 1 and discussed in citations herein above).

Claims 13 and 38 is taught as in the citations above.

In regards to claims 14 and 39, '263 differs from the claimed invention by not disclosing wherein the second part is made of stainless steel.

However, Erdman teaches wherein the second part is made of stainless steel (col. 6, lines 18-20, wherein stainless steel is a well known chemically inert material).

Erdman modify '263 by providing a two part insert of different materials.

Since both '263 and Erdman teach target chambers, it would have been obvious to one of ordinary skill in the art to have the two part arrangement of Erdman in '263 at the time the invention was made because it would provide for a cooling fluid channel that draws heat away from the rear window 64 and thus from the liquid target (col. 7, lines 44-52). Further the claim would have been obvious because the substitution of one known element (i.e. integral insert) with another (two part holder body and window insert) would have yielded predictable results to one of ordinary skill in the art at the time of the invention (i.e. cooling the rear window).

In regards to claim 17, '263 teaches filling the cavity volume of the irradiation cell with about 50% of target material before starting irradiation (because the cavity container can be filled, it is capable of being filled to 50% of its volume).

In regards to claims 20 and 40, '263 teaches wherein the cell further comprises a supply tube for a cooling medium and, in connection with the supply tube, a diffuser device mounted on one end of the supply tube (fig. 1, supply tube 10 and diffuser 3), the



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diffuser device surrounding the first part, the diffuser element being configured to guide the cooling medium around the first part (page 4, lines 23-27), and wherein the second part surrounds both the first part and the diffuser element in a manner to form a return path for the cooling medium between the diffuser element and the second part (see figure 1).

In regards to claim 21, '263 teaches an irradiation cell (fig. 1) for producing a radioisotope of interest through the irradiation of a target material by a particle beam (page 2, lines 8-12), the irradiation cell comprising a target body (page 5, line 14), a diffuser for providing a path for a cooling medium (page 4, lines 25-27), and a removable metallic insert (fig. 1,8, figure 2 shows an exploded view thus removable, further an insert is removable by definition) comprising a cavity designed to house the target material (page 4, lines 10-11 and page 4, lines 28-30 teach the cavity holds the target and the cavity is made with an insert), the cavity closed by an irradiation window (page 4, lines 10-11 teach a charged particle beam sent to a target within a cavity, thus the cavity must inherently be closed by an irradiation window to allow the charged particle beam access to the cavity), the metallic insert configured to be inserted in and removed from the target body (where an insert can be inserted, it can be removed from the body, thus the limitation is interpreted to be met), the metallic insert comprising being composed of at least a first part (the insert part forming the target cavity is the first part) and a second part (portion of the insert forming the cooling channel see page 5, lines 7-14), the first part forms a cavity that is elongate in a direction parallel to the particle beam that irradiated the target (fig. 1, 1 also see page 4, lines 10-11) and the

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second part being a generally cylindrical hollow member (second part surrounding diffuser, as seen in figure 1, also see page 5, lines 7-14) comprising a material selected from the group consisting of titanium (page 4, lines 28-29), with the second part disposed around at least a portion of the elongate cavity of the first part and the first and second parts forming a channel configured to guide a cooling medium (page 5, lines 7-14 and as seen in figure 1).

'263 differs from the claimed invention by not disclosing wherein the removable metallic insert comprises at least two separate metallic parts of different materials, the first part comprising a material selected from the group consisting of niobium and tantalum.

However, Zeisler teaches wherein the removable metallic insert comprises at least two separate metallic parts of different materials, the first part comprising a material selected from the group consisting of niobium and tantalum (fig. 2, page 451, wherein the first part is the niobium target chamber 5 and the second part is the holder ring 3).

Also Erdman wherein the removable metallic insert (fig. 3, 56 is inserted between elements 68 and 40) comprises at least two separate metallic parts of different materials, the first part comprising a material selected from the group consisting of niobium and tantalum (fig. 3, 56 and 64, wherein 64 is made of niobium (col. 5, lines 63-65) and 56 is made of any other chemically inert material, like silver (col. 6, lines 17-28)).

Zeisler or Erdman modify '263 by providing a two part insert of different materials.

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Since both '263 and Zeisler teach target chambers, it would have been obvious to one of ordinary skill in the art to have the two part arrangement of Zeisler in '263 at the time the invention was made because it would provide cooling water to all sides of the target chamber (see section 2 on page 450). Further the claim would have been obvious because the substitution of one known element (i.e. integral insert) with another (two part ring and chamber insert) would have yielded predictable results to one of ordinary skill in the art at the time of the invention (i.e. cooling to all sides of the chamber).

Since both '263 and Erdman teach target chambers, it would have been obvious to one of ordinary skill in the art to have the two part arrangement of Erdman in '263 at the time the invention was made because it would provide for a cooling fluid channel that draws heat away from the rear window 64 and thus from the liquid target (col. 7, lines 44-52). Further the claim would have been obvious because the substitution of one known element (i.e. integral insert) with another (two part holder body and window insert) would have yielded predictable results to one of ordinary skill in the art at the time of the invention (i.e. cooling the rear window).

Claim 31 is broader in scope than independent claim 1 and is therefore rejected for the same reasons above.

Claim 41 is rejected for the same reasons cited above in claim 21. Further .263 teaches wherein the cell further comprise a supply tube configured to supply a cooling medium and, in connection with the supply tube, a diffuser device mounted on one end of the supply tube, the diffuser device surrounding the first part, the diffuser element

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being configured to guide the cooling medium around the first part, and wherein the second part surround both the first part and the diffuser element in a manner to form a return path for the cooling medium between the diffuser element and the second part (page 4, lines 23-27, page 5, lines 7-14 and figure 1, wherein the first part of insert forms the cavity and the second part of insert 8 forms the cooling channel and surround the cavity 1 and the diffuser 3).

Claims 4, 5, 7, 8, 12, 23-26, 30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over BE 1011263 A6 (translation submitted by applicant on 12/16/2009)(herein '263) and Zeisler et al. (Zeisler et al., "A water-cooled spherical niobium target for the production of [<sup>18</sup>F]fluoride", Applied Radiation and Isotopes 53 (2000) 449-453)(copy of publication submitted herewith) or in alternate Erdman and further in view of Schlyer et al. (USPN 5,917,874).

In regards to claims 4, 5, 7, 8, 12, 23-26, 30 and 33-36 the combined invention fails to teach coupling of the two parts by o-rings gold foil, bolts, and welding.

Schlyer et al. teaches coupling by bolts (col. 4, lines 18-22). Although Schlyer et al. only describes coupling by bolts, fixing means such as gold foil, bolts and welding are commonly used in assembling devices and integration is part of the common knowledge of a skilled person. Thus having such fixing means would have been obvious to one of ordinary skill in the art because the substitution of one known element for another would have yielded predictable results.

Schyler modifies the combined invention by providing fixing means between two parts.

Since both the combined invention and Schyler teach irradiating target chambers, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the fixing means of Schyler in the combined device because the simple substitution of one known element for another (i.e. integral parts for two separate parts and joining them therein) would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Logie whose telephone number is 571-270-1616. The examiner can normally be reached on 7:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Kim can be reached on 571-272-2293. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. L./  
Examiner, Art Unit 2881

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